

**IN THE SPECIFICATION**

On page 1, immediately following the title, please insert the following sentence:

This is a nationalization of PCT/EP04/005115 filed May 13, 2004 and published in German.

A Substitute Specification is attached which includes the above amendments. No new matter is added.

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Fresenius Medical Care Deutschland GmbH  
D-62352 Bad Homburg

BLOOD TREATMENT EQUIPMENT

This is a nationalization of PCT/EP04/005115 filed May 13, 2004 and published in German.

The invention relates to blood treatment equipment comprising a blood treatment device which is part of an extracorporeal blood circulatory system according to the preamble of claim 1.

Various devices are known for the extracorporeal treatment of blood. In these devices blood is passed via a blood supply line from a patient to a blood treatment device and from there is passed back to the patient via a blood return line. The blood treatment device can, for example, be a haemodialyser or haemofilter, a blood oxygenator, a blood adsorber or a blood centrifuge. Such devices comprise actuators for controlling the blood treatment which are controlled by a control unit of the blood treatment equipment for the specific sequence of the blood treatment.

As a result of the numerous possible uses of this equipment and necessary safety measures, this equipment is relatively complex. For the operator there is increasingly the risk of the display and input interface being unclear. In view of the availability of new media, touch screens are increasingly being used for display and input units of such equipment. Thus, EP 0 904 788 A1 discloses the use of a touch screen to facilitate the operation of the equipment with the aid of a graphical image of the components of the haemodialysis equipment.

US 5,609,770 discloses an operator-machine interface with a touch screen for a haemodialysis device in which the focus is on the input of parameters and in which individual parameters are divided into groups. The input of parameters for a haemodialysis treatment using a touch screen is also the subject matter of EP 0 623 357 A1. The input and reproduction of specific information on an extracorporeal drip chamber in a haemodialysis treatment using a touch screen is the subject matter of US 5,858,239.

In an extracorporeal blood treatment a plurality of temporally successive modes are passed through. Apart from the actual blood treatment mode, there is a preceding blood treatment preparation mode and a subsequent blood treatment after-preparation mode. In the blood treatment preparation mode the extracorporeal blood circulatory system is prepared for the blood treatment mode, by removing air or another medium from the extracorporeal circulatory system and introducing an isotonic filling fluid, generally sodium chloride solution, into the extracorporeal blood circulatory system. At the end of a blood treatment the blood located in the extracorporeal blood circulatory system is to be re-infused into the patient during a blood treatment after-preparation mode.

Starting from the known haemodialysis equipment, the invention has set itself the object of simplifying the operation of a blood treatment device using a touch screen taking special account of the temporally successive blood treatment modes.

According to the teaching of the invention, this object is solved by a blood treatment device having the features of claim 1. Advantageous embodiments are the subject matter of the dependent claims.

Further details and advantages of the invention are described in detail with reference to an exemplary embodiment shown in the drawings. In this embodiment the blood treatment device is a haemodialysis device. In the figures:

Fig. 1 is a highly schematic view of the haemodialysis device;

Fig. 2 is a first view of a touch screen of the haemodialysis device with various mode means, wherein the mode means "blood system" is selected;

Fig. 3 is a second view of the touch screen of the haemodialysis device with various mode means, wherein the mode means "preparation" is selected;

Fig. 4 is a third view of the touch screen of the haemodialysis device with various mode means, wherein the mode means "treatment" is selected;

Fig. 5 is a fourth view of the touch screen of the haemodialysis device with various mode means, wherein the mode means "re-infusion" is selected;

Fig. 6 is a fifth view of the touch screen of the haemodialysis device with various mode means, wherein the mode means "purification" is selected;

The structure of a haemodialysis device is first explained briefly with reference to Figure 1. In haemodialysis, blood is supplied in an extracorporeal circulatory system via a blood supply line 5 to a blood purification element implemented as a haemodialyser 1. In the haemodialyser 1 a

semi-permeable membrane 2 generally implemented in the form of many hollow fibres separates a first chamber 3, which is part of the extracorporeal blood circulatory system, from a second chamber 4 which is part of a dialysis fluid circulatory system. Substances to be removed from the blood pass through the semi-permeable membrane 2 into the dialysis fluid and are removed by said fluid. At the same time, an excess quantity of fluid can be ultrafiltered from the blood via a pressure gradient and removed by means of the outflowing dialysis fluid.

In the blood supply line 5 blood is transferred by a blood pump 6 configured as a roller pump. The blood leaves the first chamber 3 of the haemodialyser 1 via the blood return line 7 to be returned back to the patient. Provided on the blood return line 7 is a venous shut-off clamp 8 with which the return of the blood can be interrupted especially in emergencies. Such emergencies can occur, for example, if air is detected in the blood return line 7 by an air detector 9. The air detector 9 also comprises means for identifying the presence of blood in the blood return line 7.

An arterial pressure sensor 10 is provided on the blood supply line 5 and a venous pressure sensor 11 is provided on the blood return line 7.

Dialysis fluid flows through the second chamber 4 of the haemodialyser, which fluid is supplied via a dialysis fluid supply line 20 from a dialysis fluid source 24 and is removed via a dialysis fluid removal line 21 to an outflow 25. The dialysis fluid is circulated by conveying and balancing devices 22 and 23 wherein the quantity of any ultrafiltrate to be removed can be registered precisely.

The person skilled in the art has various arrangements at his disposal for implementing the conveying and balancing

devices 22 and 23 so that further details are not given at this point. The same applies to the provision of dialysis fluid by the dialysis fluid source 24. As an example, reference is made to a balance chamber system such as that described in US 4,267,040.

Numerous possibilities for the use of actuators and sensors in a haemodialysis device are also generally available to the person skilled in the art without it being necessary to go into detail here. The diagram in Fig. 1 is restricted to a few of these elements which are sufficient for explaining the invention.

The haemodialysis device is controlled and monitored by a control unit 30. For this purpose the control unit 30 is connected to the individual actuators and sensors of the equipment using signal leads. For the actuators and sensors shown in Fig. 1 this is indicated by reference numbers which have an apostrophe next to the reference number of the relevant actuator or sensor and which for the sake of clarity are only indicated at the control unit 30.

The control unit 30 is connected to an output and input unit 32 via a data link 31. The output and input unit 32 comprises a touch screen 33. Information notified by the control unit 30 is displayed on the touch screen and at the same time, data entered by an operator via the touch screen is passed on to the control unit 30.

Figure 2 shows a first view of the touch screen 33 of the haemodialysis device. At the lower edge of the touch screen are various mode means 40 in an adjacent row. The mode means 40 comprise various types of mode means.

Firstly there are blood treatment preparation means 41a and 41b, blood treatment means 42 and blood treatment after-preparation means 43a and 43b, i.e., these mode means

relate to time modes before a blood treatment - a haemodialysis treatment in this case -, the actual blood treatment and after a blood treatment. In each of these modes the haemodialysis device runs through specific process steps, with the modes proceeding in a certain time sequence.

Furthermore, supplementary mode means 44a, 44b and 45a and 45b are provided to make it possible to enter supplementary information at a plurality of time points. The meaning of the individual modes is described in detail in the continuation of the description.

Arranged on the touch screen 33 above the mode means 40 is a region 50 on which various views are to be seen according to the operating mode. In the edge regions 51, 52 further input and/or output means (for example, means 53 for the blood pump 6) are provided to make it possible to make specific data inputs and display desired information.

These edge regions can have the same structure regardless of the operating mode or they can depend thereon. Since this part of the touch screen is of secondary importance for the explanation of the invention, this is not discussed in further detail at this point.

At the beginning of the haemodialysis treatment the haemodialysis device switches into the "blood system" mode (Figure 2). If the device does not identify an inserted blood hose by means of a suitable sensor, e.g. a mechanical contact sensor 12 on the blood pump 6, this mode is automatically displayed by the control unit 30. Otherwise it is skipped and the control unit 30 triggers the selection of the temporally successive preparation mode.

In the blood system mode a graphical image of a blood hose system mounted on the haemodialysis device is shown on the

display area 50 to facilitate the insertion of a blood hose system for the user. In this case, the haemodialyser 1, the blood supply line 5, the blood pump 6, the arterial pressure sensor 10, the blood return line 7, the venous clamp 8, the air and blood detector 9 and the venous pressure sensor 11 can be identified in accordance with Figure 1.

The display and input unit 32 can represent the mode means 40 on the touch screen 33 by three types of symbols.

Firstly, those mode means which can be selected manually via the touch screen 33 in the instantaneous mode are represented in a first type of symbol. For the view shown in Figure 2 this relates to the mode means 44a, 44b, 43b and 45. The mode means which displays the currently selected mode (blood system mode means 41a in Figure 2) is displayed in a second type of symbol. A third type of symbol is used for the remaining mode means which are deactivated in the current mode. In Figure 2 these are the mode means 41b, 42 and 43a.

On the left side of the view of the touch screen the measured values of the arterial and venous pressure sensors 10 and 11 are displayed in the form of bar displays 52 and 53.

After the control unit 30 has detected the presence of a correctly inserted hose system using the sensor 12, according to the invention it triggers the end of the blood system mode and the beginning of the temporally following preparation mode. The display and input unit 32 is in this case instructed to represent the mode means 40 accordingly.

The mode means 41b is now selected automatically and the view changed to that shown in Figure 3.



The view in region 50 of the touch screen 33 now shows in the data strip 55 a view of parameters such as are representative for the progress of the flushing of the blood hose system. During the flushing, for example, a bag containing physiological saline solution is connected to the blood supply line 5. The blood return line 7 leads to an outflow. At least 4 litres of sodium chloride solution are available for satisfactory flushing. By actuating the blood pump activating means 56 the blood pump is switched on with a previously set delivery flow. The data in the data strip 55 then show the respective current values. If a sufficient quantity of flushing fluid has been conveyed by the extracorporeal circulatory system, the blood pump 6 is automatically stopped by the control unit 30 on reaching the pre-determined flushing target volume. It is also possible to end the flushing manually by the blood pump activating means 56 should a smaller flushing volume be considered as sufficient.

The operator now connects the blood supply line 5 and the blood return line 7 to a blood vessel in the patient. The blood pump 6 must then be set in operation again using the blood pump activating means 56. As soon as blood is identified in the blood detector 9, the blood treatment can begin. For this purpose the blood detector 9 has an optical detector which examines the colour of a medium in the blood return line 7 by a suitable choice of wavelength using the transmitted light method. The corresponding signal is received by the control unit 30 which thereby selects the next temporally successive operating mode and communicates this to the display and input unit 32 for the corresponding display. The view shown in Figure 4 is then displayed on the touch screen 33.

The temporal mode now introduced automatically is the treatment mode, i.e., the actual haemodialysis treatment begins. In the treatment mode the data strip 57 is

displayed on the display area 50. Data strip 57 reproduces treatment progress parameters such as the elapsed treatment time and the ultrafiltration quantity already removed.

Basic values of the dialysis fluid composition such as the sodium and bicarbonate concentration are also displayed.

If a pre-determined treatment target is achieved, e.g. a total ultrafiltration quantity to be removed, the haemodialysis treatment is stopped by the control unit 30 by stopping the blood pump 6. According to the invention, the temporally successive re-infusion mode is also initiated by the control unit 30. For this purpose the display and input unit 32 is instructed by the control unit 30 to change to the view in accordance with Figure 5.

The operator now separates the blood supply line 5 from the patient and re-connects the bag containing isotonic sodium chloride solution to this line. In the data strip 58 data on the re-infusion to take place are displayed by analogy with the data strip 55. The re-infusion can be started with the aid of the blood pump activating means 59. The control unit 30 controls the blood pump 6 such that a pre-determined blood hose volume of 150 ml in this example is conveyed in order to return the blood in the extracorporeal circulatory system back to the patient via the blood return line 7. After conveying the pre-determined quantity of fluid, the control unit 30 according to the invention initiates the next temporally successive mode - the purification mode.

In the purification mode the display and input unit 32 displays the view which can be seen in Figure 6. The patient is now completely separated from the haemodialysis device by the operator before flushing and disinfection steps are initiated. During the purification operating parameters are displayed on the display area 50. The

haemodialysis device has thus reached the end of the individual temporal treatment modes for a haemodialysis treatment.

The embodiment of the haemodialysis device according to the invention simplifies the operator management by the automatic selection of the mode means described with the introduction of temporally successive operating modes and thereby helps to avoid incorrect operations. In addition, an arrangement of the mode means corresponding to the time sequence improves the clarity of the touch screen elements. This also applies to the permanent visibility of the individual mode means in all views regardless of the operating mode, which represents a particularly advantageous embodiment. As a result of the automatic selection of subsequent operating modes, the operator is additionally unburdened since fewer inputs are required.

This particularly applies in cases where, in addition to changing the representation on the touch screen at the beginning of a subsequent temporal mode, actuators of the blood treatment device are also automatically set in motion. In the example shown this was the case on transition from the preparation mode to the treatment mode.

In order to increase the clarity it can be provided when controlling the touch screen to vary the appearance of the symbols used for the individual mode means. The mode means 40 in Figures 2 to 6 accordingly varies in height with the highest value for the blood treatment means 42. Towards the blood treatment preparation means 41a and 41b and the blood treatment after-preparation means 42a and 42b, the height decreases in order to give these three temporal regions an additional clarity, with the blood treatment means 42 being emphasised.

The mode means 40 can comprise further supplementary mode means 44a, 44b, 45a and 45b not mentioned so far. In the example shown in Figures 2 to 6 treatment values differing from the treatment base values can be input using the dialysate mode means 44a and the ultra-filtrate mode means 44b. Manual selection of these mode means is especially suitable during the preparation of a haemodialysis treatment. For this reason these mode means are arranged on the blood treatment preparation side of the mode means 40. However, it is also possible to change the corresponding treatment parameters such as, for example, dialysis liquid flow, ultrafiltration quantity, treatment time etc. manually during a haemodialysis treatment before the end of the treatment by selecting these mode means.

The options mode means 45a is reserved for the extension functions of the haemodialysis equipment which likewise influence the course of a haemodialysis treatment or at least make available further measured data for their monitoring. The system mode means 45b concerns equipment settings such as the loudness of a loudspeaker or the brightness of the display which can be changed at any time and which are not directly related to the blood treatment.